



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0187]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with premarket approval of medical devices.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0187 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices." Received comments, those filed in a timely manner

(see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Approval of Medical Devices

OMB Control Number 0910-0231--Revision

This information collection supports implementation of statutory and regulatory requirements that govern premarket approval of medical devices. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of

Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act (21 U.S.C. 360e) in order to obtain marketing approval. Please note that PMA requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices and some Class III preamendment devices may require a Class III 510(k). See the PMA Historical Background webpage at <https://www.fda.gov/medical-devices/premarket-approval-pma/pma-historical-background> for additional information. Section 515A of the FD&C Act (21 U.S.C. 360e-1) governs pediatric uses of devices.

The PMA is the most stringent type of device marketing application required by FDA. Applicants must receive FDA approval of a PMA application prior to marketing the device. PMA approval is based on a determination that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Respondents to the information collection are PMA applicants, or persons who own the rights, or otherwise have authorized access, to the data and other information to be submitted in support of FDA approval. This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. The applicant is often the inventor/developer and ultimately the manufacturer. A Class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and may not be marketed.

FDA regulations in part 814 (21 CFR part 814) implement section 515 and 515A of the FD&C Act and establish procedures for the premarket approval of medical devices intended for human use, including the submission of information concerning use in pediatric patients.

Regulations in part 814, subpart A (§§ 814.1 to 814.19) set forth general provisions pertaining to the confidentiality of data and information submitted to FDA in a PMA, research conducted outside the United States, service of orders, and product development protocols. Provisions in part 814, subparts B and C (§§ 814.20 to 814.47) establish format and content elements that must be included in an application, explain submission and review schedules, and address the withdrawal and temporary suspension of a PMA. Postapproval requirements, including reports required under 21 CFR part 803 (medical device reporting), are covered in regulations in part 814, subpart E (§§ 814.80 to 814.84). Burden attributable to information collection associated with regulations in part 814, subpart H (§§ 814.100 to 814.126) pertaining to Humanitarian Use Devices is currently approved in OMB control number 0910-0332.

For operational efficiency, we are revising the information collection to include burden that may be associated with recommendations found in the Agency guidance document entitled, “Providing Information about Pediatric Uses of Medical Devices” (May 2014), currently approved in OMB control number 0910-0748. The guidance document describes how to compile and submit the readily available pediatric use information required under section 515A of the FD&C Act. The guidance document is available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices>.

Relatedly, we are revising the information collection to include burden that may be associated with the submission of information on pediatric use of medical devices under section 515A of the FD&C Act, also currently approved in OMB control number 0910-0748. Section 515A(a) of the FD&C Act requires applicants who submit information to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. This information allows FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition

that the device is intended to treat, diagnose, or cure and the review time for each such device application.

We are also revising the information collection to include burden applicable to implementing requirements under section 402(j)(5)(B) of the Public Health Service (PHS) Act (42 U.S.C. 282(j)(5)(b)), and set forth in regulations at 42 CFR part 11 (see 81 FR 64981, September 21, 2016). Specifically, applications under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers. We have developed Form FDA 3674 (“Certifications to Accompany Drug, Biological Product, and Medical Device Applications/Submissions”), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions>, for respondents to submit the requisite information.

Respondents can make single submissions in an electronic format that includes eCopies, submissions submitted on CD, DVD, or flash drive and mailed to FDA and eSubmissions, submissions created using an electronic submission template (e.g., “electronic Submission Template and Resource” (eSTAR)). Consistent with our authority in section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), and performance goals found in our current Medical Device User Fee Amendments Commitment Letter, we developed eSTAR for use through the Center for Devices and Radiological Health Customer Collaboration Portal. We use eSTAR as a tool to facilitate the preparation of submissions in electronic format (available on FDA’s website at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program> and identified as Form FDA 4062 “Electronic Submission Template and Resource (eSTAR)” (for Non-In Vitro Diagnostic submissions) and form FDA 4078 “Electronic Submission Template and Resource (eSTAR)” (for In Vitro Diagnostic submissions)). We

believe respondents' use of eSTAR will significantly reduce burden attendant to application submissions by providing a uniform format for requisite elements and by enhancing user interface through the use of modernized technology.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity/21 CFR or FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Premarket Approval Submissions ("traditional" preparation; eCopy submission):					
21 CFR Part 814, Premarket Approval of Medical Devices					
Subpart A--General					
Research conducted outside the United States (814.15(b))	20	1	20	2	40
Subpart B--Premarket Approval Application (PMA)					
PMA application (814.20)	40	1	40	654.6	26,184
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C))	10	1	10	0.5 (30 minutes)	5
PMA amendments and resubmitted PMAs (814.37(a)-(c) and (e))	1,356	1	1,356	167	226,452
PMA supplements (814.39(a))	762	1	762	0.983 (59.11 minutes)	45,048
Special PMA supplement--changes being affected (814.39(d))	75	1	75	6	450
30-day notice (814.39(f))	1,181	1	1,181	16	18,896
Subtotal Parts A and B					317,075
Subpart C--FDA Action on a PMA					
Panel of experts request (814.42 and 515(c)(3) of the FD&C Act)	1	1	1	30	30
Subpart E--Postapproval Requirements					
Postapproval requirements (814.82(a)(9))	121	1	121	135	16,335
Periodic reports (814.84(b))	764	1	764	10	7,640
Total Subpart E					24,005
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674--Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"					
Certification to accompany PMA submissions (Form FDA 3674)	40	1	40	0.75 (45 minutes)	30
FD&C Act section 515A Pediatric Uses of Devices:					
Pediatric information in a PMA, PDP, or PMA supplement	944	1	944	2.10	1984
Pediatric use information outside approved indication	800	1	800	0.5 (30 minutes)	400
Subtotal	1,744	1	1,744		2,384
Premarket Approval Submissions (eSTAR preparation; eCopy submission):					
eSTAR setup	30	1	30	0.08 (5 minutes)	2
Total					343,496

Table 1.--Estimated Annual Reporting Burden¹

Activity/21 CFR or FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
-------------------------------------	--------------------	---------------------------------	------------------------	-------------------------------------	-------------

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2019 through 2021 and our expectation of submissions to come in the next few years. We also account for referrals of PMAs to a panel for review, as provided for under § 814.44(a). FDA may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. We have adjusted our figures to reflect an overall decrease, which we attribute to respondents' use of modernized submission technologies including eSTAR. At the same time, we include in our estimate an initial burden attributable to respondents who need to set up an eSTAR account for the first time.

Table 2.--Estimated Annual Recordkeeping Burden¹

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Maintenance of records (814.82(a)(5) and (a)(6))	552	1	552	17	9,384

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The regulations require the maintenance of records, which are used to trace patients, and the organization and indexing of records into identifiable files to ensure a device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA. Currently there are 815 active PMAs that could be subject to these requirements, based on FDA data, and approximately 33 new PMAs are approved each year. We estimate our annual recordkeeping burden based on an average of 552 PMA holders. The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required under 21 CFR part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Cumulatively, our adjustments reflect only a slight increase to the estimated burden for the information collection.

Dated: January 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-01849 Filed: 1/27/2023 8:45 am; Publication Date: 1/30/2023]